

**LIBELED:** 9-13-57, Dist. Utah.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statements "Each tablet contains .625 mg. [or 1.25 mg.] of estrogens in their naturally occurring water-soluble conjugated form" were false and misleading.

**DISPOSITION:** 12-27-57. Default—destruction.

**5910. Conjugated estrogen tablets.** (F.D.C. No. 42755. S. No. 28-470 P.)

**QUANTITY:** 1 drum containing 20,000 tablets at Houston, Tex.

**SHIPPED:** 11-25-58, from Philadelphia, Pa., by Lustgarten Laboratories, Inc.

**RESULTS OF INVESTIGATION:** Analysis showed that the total estrogen content per tablet corresponded to not more than 0.70 milligram of sodium estrone sulfate.

**LIBELED:** 12-31-58, S. Dist. Tex.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess, namely, that each tablet contained an amount of estrogens equivalent to 1.25 milligrams of sodium estrone sulfate; and 502(a)—when shipped and while held for sale, the label statement "Conjugated Estrogens 1.25 Mgm. \* \* \* expressed in terms of an equivalent quantity of Sodium Estrone Sulfate" was false and misleading.

**DISPOSITION:** 2-20-59. Default—destruction.

**5911. Dexobese timed disintegration capsules.** (F.D.C. No. 42781. S. No. 34-900 P.)

**QUANTITY:** 9 500-capsule btl., 24 100-capsule btl., and 71 30-capsule btl. at Philadelphia, Pa.

**SHIPPED:** 10-10-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

**RESULTS OF INVESTIGATION:** The article was shipped in bulk as described above and after its receipt by the consignee at Philadelphia, Pa., was re-packaged in the above-mentioned bottles.

Analysis showed that the article contained 80.7 percent of the 15 mgs. of amphetamine sulfate per capsule which it was represented to have.

**LIBELED:** 1-9-59, E. Dist. Pa.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess, since the article contained less than the declared amount of amphetamine sulfate.

**DISPOSITION:** 2-4-59. Default—destruction.

**5912. Para Dex Fifteen capsules and Para Barb 3 capsules.** (F.D.C. No. 42796. S. Nos. 41-592/3 P.)

**QUANTITY:** 57 100-capsule btl., and 11 250-capsule btl., of *Para Dex Fifteen capsules*, and 97 100-capsule btl., of *Para Barb 3 capsules*, at Salem, Oreg.

**SHIPPED:** 10-6-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

**LABEL IN PART:** (Btl.) "Para Dex Fifteen Capsules Three Releases \* \* \* Each Para Dex Fifteen Capsule contains 15 mg. of Dextro-Amphetamine Sulfate to release uniformly over a period of six to ten hours," and "Para Barb 3 Capsules \* \* \* Each Para Barb 3 Capsule contains: Phenobarbital 100 mg. A brand of time disintegration capsule."

**RESULTS OF INVESTIGATION:** The articles were shipped in bulk as described above and upon receipt at Salem, Oreg., were repacked into the above-mentioned bottles and labeled as described above by the dealer.

Examination showed that 70 percent of the labeled amount of dextro-amphetamine in the *Para Dex Fifteen capsules* was released in a two-hour period; and that the *Para Barb 3 capsules* contained 75 percent of the labeled amount of phenobarbital.

**LIBELED:** 2-2-59, Dist. Oreg.

**CHARGE:** 501(c)—when shipped, the quality of the *Para Dex Fifteen capsules* fell below that which they were represented to possess since the dextro-amphetamine ingredient was not released at a uniform rate over a six- to ten-hour period, and the strength of the *Para Barb 3 capsules* differed from that which they were represented to possess since the article contained only 75 percent of the labeled amount of phenobarbital; and 502(a)—the label statements "Each Para Dex Fifteen Capsule contains 15 mg. of Dextro-Amphetamine Sulfate to release uniformly over a period of six to ten hours" and "Each Para Barb 3 Capsule contains: Phenobarbital 100 mg." were false and misleading.

**DISPOSITION:** 3-12-59. Default—destruction.

**5913. Martabs No. 2.** (F.D.C. No. 42830. S. No. 10-336 P.)

**QUANTITY:** 43 500-tablet btls. at Pittsburgh, Pa.

**SHIPPED:** 12-5-58 and 1-9-59, from Mansfield, Ohio, by Caldwell & Bloor Co.

**LABEL IN PART:** "Martabs No. 2 \* \* \* Distributed \* \* \* by The Caldwell and Bloor Co. Mansfield, Ohio. Each Tablet Contains: Phenobarbital \* \* \* 16 mg. Calcium Carbonate 0.5 gm. Magnesium Oxide 0.25 gm. Atropine Sulfate 0.2 mg."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained between 56 and 82 percent of the labeled amount of phenobarbital.

**LIBELED:** 2-11-59, W. Dist. Pa.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it was represented to possess; and 502(a)—the label statement "Each Tablet Contains: Phenobarbital 16 mg." was false and misleading.

**DISPOSITION:** 4-17-59. Default—destruction.

**5914. Rubber prophylactics.** (F.D.C. No. 42975. S. No. 10-667 P.)

**QUANTITY:** 63 gross ctns., 12 pkgs. each, at Syracuse, N.Y.

**SHIPPED:** 9-19-58, from Akron, Ohio, by Killashun Sales Div. of the Akwell Corp.

**LABEL IN PART:** (Pkg.) "Xcello's prophylactics \* \* \* Mfg. by The Killian Mfg. Div. of the Akwell Corp. Akron, Ohio Contents One Dozen."

**RESULTS OF INVESTIGATION:** Examination showed that 1 percent contained holes.

**LIBELED.** 4-16-59, N. Dist. N.Y.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Prophylactics \* \* \* Sold for Prevention of Disease Only" was false and misleading.

**DISPOSITION:** 5-26-59. Default—destruction.